

Remarks/Arguments

The prior office action maintained the restriction requirement, pointed out that new claims 39-41 are directed to non-elected inventions, and rejected the claims as allegedly not enabled. Claims 1, 3-13, 20-25 and 31-41 are currently pending. Claims 13, 20-25, 31 and 39-41 were withdrawn by the examiner as directed to a non-elected invention.

*Restriction Requirement*

In maintaining the restriction requirement the examiner characterized Y-B-A-X as drawn to a dipeptide and Z-C-B-A-X' as drawn to a tri-peptide. Y-B-A-X is a generic structure allowing for different numbers of amino acids, such as di- and tri-peptides, and possibly additional amino acids. For example, when Y equals Z-F-E-D-C- the overall structure for Y-B-A-X becomes Z-F-E-D-C-B-A-X, where "A", "B" and "C" are amino acids as described in claim 1, and "D-E-F" can be optionally present amino acids as described in claim 1.

*35 U.S.C. § 112 (Enablement)*

Claims 1, 3-12 and 32-38 stand rejected as allegedly not enabled. The rejection only addresses claim 1. For example, only claim 1 is referred to by the examiner in discussing "Breadth of the claims", "The state of the prior art", "The level of predictability in the art", "The amount of guidance present", "The existence of working examples", and "The quantity of experimentation necessary". The rejection is respectfully traversed.

Enablement requires the specification to teach the skilled artisan to make and use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Determining what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *Id.* The test for undue experimentation is not merely quantitative. *Id.* A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Id.*

The guidance provided in the application enables the claimed invention by directing the skilled artisan to a particular genus, illustrating the ability of representative species of the claimed genus to inhibit HCV protease activity, providing guidance on making additional compounds within the genus, and providing guidance on testing compounds. Such guidance is found in the specification, for example, as follows: pages 73-92 illustrates different examples of different types of inhibitors covered by various claims and the ability of such inhibitors to affect protease activity; pages 33-42 illustrates general methods for synthesizing inhibitors; pages 43-69 illustrates specific methods for synthesizing particular inhibitors; and pages 70-72 illustrates techniques that can be used evaluate inhibitor activity.

The rejection indicates the level of skill in the art is an M.D. or Ph.D. Such a highly trained artisan could readily employ techniques known in the art and described in the application to produce and test compounds within the claimed genus beyond those specifically exemplified.

The rejection appears to only take into account specific examples of compounds synthesized and testing in evaluating enablement. For example, the examiner points to a range of IC50 values for different compounds provided in the specification, and appears to argue that enablement is limited to only those compounds specifically made and tested.

The application provides the skilled artisan with both specific and general guidance for practicing the claimed invention. The application directs the skilled artisan to a genus whose members, based on the present application, have an increased likelihood to act as HCV protease inhibitors.

Predictability of the claimed invention needs to be evaluated taking into account the teaching provided in the application. The application itself provides evidence that numerous compounds within the claimed genus inhibit NS3/NS4a activity. Such compounds provide a higher level of likelihood that related compounds can also inhibit protease activity, than existed prior to the present application.

The particular activity level of a compound can readily be determined using techniques known in the art or described in the application. Given the overall teaching provided in the application and the high level of skill in the art, such determination involves routine experimentation.

Accordingly the claims are in condition for allowance. Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By Sheldon O. Heber  
Sheldon O. Heber  
Reg. No. 38,179  
Attorney for Applicants

Merck & Co., Inc.  
P.O. Box 2000  
Rahway, NJ 07065-0907  
(732) 594-1958